



## ATTACHMENT A

### Remarks

Claims 24-63 are pending in the present application. By this Amendment, in conjunction with the RCE filed, Applicant has amended claims 24 and 43. Applicant respectfully submits that the present application is in condition for allowance based on the discussion which follows.

As an initial point, Applicant is grateful for the Examiner extending a personal interview to his representative, Mr. Stephen Weyer, on 25 September 2006. In accordance with that interview, Applicant has amended the claims, as discussed, and prepared the following remarks.

Claims 24 and 43 were rejected under 35 U.S.C. § 112, second paragraph for omitting the word, "and" between "hydrogen" and "carbohydrate" in the Markush group. By this amendment, Applicant has amended claims 24 and 43, thereby obviating the rejection under 35 U.S.C. § 112.

Claims 24-63 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cham et al. (Cancer Letters) (hereinafter "Cham"). In accordance with the Examiner Interview, by this Amendment, Applicant has amended claims 24 and 43 to now recite that the removed free sugar is a degradation product of the glycoalkaloid from the preparation. Accordingly, the present method is further distinguishable from Cham as being directed to a method for preparing a glycoalkaloid preparation which includes removing free sugars, which are degradation products of the glycoalkaloid, from the preparation.

As discussed during the interview, novelty of the present invention is based on the discovery that the glycoalkaloid degrades to produce free sugar and that the

presence of the free sugar degradation product affects the purity of the glycoalkaloid preparation. Prior to the present invention, it was not known that the glycoalkaloid preparation was degradable to produce free sugar. Accordingly, the present method is directed to removing the newly discovered free sugar present in a glycoalkaloid preparation, as claimed.

Applicant respectfully submits that the present method is not obvious from Cham, as Cham fails to teach or suggest removing the free sugar from a glycoalkaloid preparation, let alone removing free sugar which is a degradation production of the glycoalkaloid preparation. Cham is directed to studying the possible role monosaccharide rhamnose conjugated to solasonine, solamargine and diglycosides of solasodine, collectively referred to as BEC, in nature of binding and/or drug delivery of the active agents in the BEC to cancer cells. To determine what role, if any, the rhamnose conjugate plays in the targeting, binding and/or uptake into the cancer cell of the glycoalkaloid compound, Cham teaches adding rhamnose to a glycoalkaloid preparation in amounts of 5, 10 and 15 mg/kg to compete with the rhamnose conjugated to the glycoalkaloid compound and thus to compete with the binding of the compound. Although Cham teaches that adding rhamnose to a glycoalkaloid preparation decreases the activity of the active agents in the BEC, Cham fails to teach or suggest removing free sugar present in a glycoalkaloid preparation since one of ordinary skill in the art would not have known that free sugar would be present in that preparation. Although Cham teaches adding sugar to a preparation, nowhere does Cham teach or suggest that free rhamnose or any sugar would be present in the preparation unless it was added extraneously. Therefore, one of ordinary skill in the art

would not know that free sugars would be present in a solasodine glycoside preparation. Accordingly, one of ordinary skill in the art would not be motivated to remove free sugar, which one of ordinary skill in the art would not expect would be present in a glycoalkaloid preparation.

Based on the foregoing, Applicant respectfully submits that claims 24-63 are not obvious in view of Cham.

In view of the foregoing, Applicant respectfully submits that the present application is in condition for allowance.